Rapid Point-of-Care (POC) Testing Bulletin No. 2

To: Nursing Home Administrators

From: COVID-19 Testing Task Force, Maryland Department of Health

CC: Local Health Officers

Subject: Obtaining Rapid POC Testing Supplies

Date: October 16, 2020

Nursing Home Administrators:

The Maryland Department of Health (MDH) has procured 250,000 rapid point-of-care (POC) antigen tests and 150 testing devices from manufacturer Becton, Dickinson and Company (BD).

Rapid POC testing supplies will be available for purchase, as supplies permit, from MDH at a cost of \$990.00/kit of 30 tests and \$325.00/testing device. Each testing device has a shelf life of two years or 3,500 tests, whichever occurs first; each test has a current shelf life of six months. Please also note that each facility wishing to obtain these supplies must have a Clinical Laboratory Improvement Amendment (CLIA) waiver and the appropriate state laboratory permit.

To obtain or change the required lab permits:

- If you already have a Maryland laboratory license and CLIA certification, fully complete a <u>change form</u> to add the COVID antigen test.
- To apply for a Maryland laboratory license, fully complete a <u>State Compliance</u> Application.
- To apply for CLIA certification, fully complete a CLIA Certification Application.

<u>Distribution Prioritization</u>: Rapid POC testing supplies will be available for purchase by MDH according to the following order of priority:

- 1. Congregate-care facilities:
 - a. Nursing Homes
 - b. Correctional Facilities
 - c. Facilities with dormitories and other residential settings
 - d. Assisted Living Facilities (ALF)
- Residential Treatment Facilities
 - a. Developmental Disability Facilities
 - b. Behavioral Health Facilities
- 3. State agencies and local health departments (LHDs)
- 4. Other private entities, including somatic healthcare providers

This order of priority is based on the following considerations:

- 1. Ability to establish an appropriate test-setting and organizational infrastructure. This infrastructure includes staffing, quality assurance/quality control, results reporting, and test management protocols. Additionally, each facility requires:
 - a. designated testing space;
 - b. CLIA waiver certification and appropriate state permit;
 - c. appropriate personnel on site to collect specimens and process samples; and
 - d. appropriate personnel to electronically report all results daily to the state, via Maryland's Health Information Exchange, CRISP. Information on how to register to use CRISP can be found here.
- 2. **Need for POC tests** as determined by:
 - a. total number of estimated at-risk and/or infected individuals -OR-
 - b. institutional need to maintain operations.
- Surrounding county positivity rate as identified by the Centers for Medicaid/Medicare Services (CMS) (current rates can be found here under heading "COVID-19 Testing"). Counties with higher positivity rates will be placed higher on the distribution list.

<u>Indicating demand</u>: Please fill out <u>this interest form</u> so that Maryland can estimate demand and determine the need for additional orders. Completion of this form does not constitute order fulfillment. For any additional questions, please email <u>MDH.RapidPOCtest@Maryland.gov</u>.